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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/089,501 | 04/22/2002 | Hiroyuki Saito | 053466-0325 | 9449 |

22428 7590 09/19/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

BURKHART, MICHAEL D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1633

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,501

Applicant(s)

SAITO ET AL.

Examiner

Michael D. Burkhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/29/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of 7/5/2005 has been entered. Claims 1-53 are pending, claims 1-8 are withdrawn and claims 9-53 are under examination.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 11-14, 16-18, 20-27, 29-32, 34-36, 38-41, 43-45, 47-50, and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by del Zoppo (5,879,677, as cited in the previous Office Action). This rejection is maintained for reasons of record and for reasons outlined below. Applicants have merely amended the claims to read on methods of treatment that use the antibodies anticipated by del Zoppo in the previous Office Action. The only recited method step is "administering a therapeutically effective amount" of the antibody. Therefore, it is considered that administration of any of the anticipatory antibodies of del Zoppo et al in such an amount to have a "therapeutic effect" is anticipatory to the instant method claims, regardless of the diseases recited in the preambles of the instant claims. This is because the functionality of the claimed compounds (anti-TF antibodies) does not change, i.e. they bind human TF and prevent coagulation. Therefore, absent evidence to the contrary, administration of anti-TF antibodies that have a therapeutical effect to treat one "hypercoagulative" disorder would be expected to have the same effect when used to treat another hypercoagulative disorder. del Zoppo teaches

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the antibodies of the instant claims for reasons made of record in the previous Office Action. del Zoppo also teaches administration of the antibodies to treat reperfusion tissue damage due to thrombosis, or new clot formation (i.e. coagulation, see column 2, lines 11-31, column 3, lines 24-44, and Example 2, beginning in column 17).

Claims 9-11, 18-20, 27-29, 36-38, and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Randolph et al (Blood, 1998, cited by applicants). The claims have been amended to recite methods as described above. For reasons set forth in the above del Zoppo rejection, administration of a therapeutically effect amount of the anti-TF antibodies is considered to anticipate the claimed methods. Randolph et al teach the antibodies of the instant claims for reasons made of record in the previous Office Action. Additionally, Randolph et al teach that administration of anti-TF antibodies to chimpanzees and baboons could block LPS-mediated intravascular coagulation (page 4167, first column, second paragraph).

Claims 9, 11-16, 18, 20-25, 27, 29-34, 36, 38-43, 45, and 47-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Sato et al (U.S. Patent 6,677,436, issued 1/13/2004).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims have been amended to recite methods as described above. For reasons set forth in the above del Zoppo rejection, administration of a therapeutically effect amount of the anti-TF antibodies is considered to anticipate the claimed methods. Sato et al teach the antibodies of the instant claims for reasons made of record in the previous Office Action. Sato et al also disclose that the antibodies are therapeutic agents for treatment of disseminated intravascular coagulation ("DIC", see abstract) and were administered to animals to achieve a therapeutic effect against DIC (column 27, lines 49-56, and Example 8, beginning in column 58).

Conclusion

No claims are allowed.

Any rejections not repeated in this Action are withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
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DAVID GUZO
PRIMARY EXAMINER